REMARKS

Claims 44-51 and 53-55 currently are pending. These claims are rejected under 35 U.S.C.§§ 101 and 112, first paragraph as lacking either a credible asserted utility or a well-established utility. The basis for this rejection is stated to be that one skilled in the art would not know how to use the invention since the invention, although recited in terms of a method claim, is in fact drawn to a nuclear receptor co-regulatory protein with no other utility than to carry out research to identify the possible diseases with which it may be associated.

The Office's comments indicate that what the invention is and how it works is not clearly stated in the claims. Applicants have redrafted the claims in an attempt to clarify that the invention is an assay method useful for identifying compounds that interact with nuclear hormone receptors that have known relationships to human disease.

The claims are not directedly merely to a nuclear co-regulatory protein for use in investigational research to determine what diseases might be affected by a group of unknown nuclear hormone receptors. Known nuclear hormone receptors also are used with the invention, therefore the well-known relationships between nuclear receptor co-regulatory proteins and the various disease states associated with them and their cognate nuclear hormone receptors and their functions (see previous response) form the basis for a clear "real world utility." The claims recite a "screening method" and contain clear method steps. The claimed screening method involves screening for a pair of molecules (one of which is a nuclear hormone receptor protein molecule, the other of which is a ligand for the nuclear hormone receptor) that interact with a nuclear receptor co-

regulatory peptide molecule based on binding with the binding region of SEQ ID NO:5.

One utility of the method is that once it is learned from the screening method that a particular nuclear hormone receptor-ligand pair interacts with co-regulatory proteins having the binding sequence of SEQ ID NO:5, then the identified ligands can be used to modify the activity of the nuclear hormone receptor. Furthermore, the assay can be used to identify other ligands that also interact with the nuclear hormone receptor and co-regulatory protein. The ligands, identified as interacting via the newly discovered binding sequence (SEQ ID NO:5), can be used as drugs that act on this system or as lead compounds in the well-known modern methods of drug discovery. All of this would be clear to a person of skill upon reading the specification and claims.

It also is known to the person of skill that nuclear hormone receptors and their function are keys to many different disease states that can be and already are being treated by ligands which modify their activity. For example, in hormone-dependent cancers such as breast cancer and prostate cancer, nuclear hormone receptor activation (estrogen and testoterone, respectively) is a key to both disease etiology and treatment. See Tenbaum and Baniahmad, *Int. J. Biochem. Cell Biol.* 29(12): 1325-1341, 1997 (attached). Hormone control therapy is a mainstay of prostate cancer treatment. Further examples of diseases treated with nuclear hormone receptor ligands include thyroid hormone receptor (hypothyroidism), vitamin D receptor (retinoblastoma), glucocorticoid receptor (rheumatoid arthritis) progesterone receptor (breast cancer) and retinoic acid receptor (retinoblastoma).

Therefore, it would be clear to anyone of ordinary skill in the art that ligands which bind to and/or interact with such nuclear hormone receptors could be used to modify the activity of

these nuclear hormone receptors for the purpose of modifying the corresponding disease states. As the Office points out, the assay can be used to identify new, not previously known nuclear hormone receptors. This utility is in addition to discovering new ligands which interact with known nuclear hormone receptors that have known roles in the etiology and treatment of important diseases. The specification and claims as originally filed clearly disclose that known nuclear hormone receptors (having known links to disease states) are contemplated for use with the inventive methods. See, for example, Examples 2 and 4 and original claim 47.

The fact that one utility of the invention is not recognized as a "real world utility by the Office does not destroy the other utilities of the invention. An assay method for identifying compounds that have a substantial utility define a "real world" context of use, and do not constitute a mere research tool with no utility outside the theoretical context. See M.P.E.P. § 2107.01. The present invention can be used, as disclosed, by the person of ordinary skill in the art in a manner which provides a benefit to the public and therefore meets the requirements of 35 U.S.C. § 101. The present invention therefore possesses a substantial and real world utility that would be apparent to any person of skill in heart upon reading the disclosures.

Applicants therefore request that the Office withdraw the rejection of the claims under 35 U.S.C. §§ 101 and 112, first paragraph on the basis of lack of utility.

Claims 44-51 and 53-55 are rejected under 35 U.S.C. § 112, first paragraph, on the basis that claimed subject matter is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention. This rejection is made on the grounds that the specifcation does not literally disclose every

protein sequence which can comprise the binding domain of SEQ ID NO:5 by providing structural properties or characteristics for the protein, other than the binding sequence upon which the inventive assay method is based.

What is conventional or well-known to one of ordinary skill in the art need not be disclosed in detail to meet the requirements for written description. M.P.E.P. § 2163 (II)(A)(3)(a). Persons of skill in the relevant art consider construction of fusion proteins and the nucleic acids that encode them to be routine. Constructing any desired nucleic acid sequence which encodes SEQ ID NO:5 therefore would be a simple matter. A person of skill would recognize (1) that the invention, an assay system based on binding to a specific, disclosed binding motif or sequence, can be performed using nuclear receptor co-regulatory peptide molecules containing that sequence and (2) that it is not necessary to disclose every potential non-binding sequence. A person of skill would be able to construct suitable and convenient nucleic acids for use with the inventive method.

The person of skill would immediately recognize that the inventors had described an assay to be performed with the SEQ ID NO:5 binding sequence since it is interaction with the binding sequence that allows the binding assay to work. To address the apparent lack of clarity in the claims with respect to this issue, Applicants have amended the claim language to specify the nuclear co-regulatory peptidic molecules that both contain and bind via the SEQ ID NO:5 sequence.

Applicants have disclosed the binding sequence upon which the assay is based and thus have shown that they possessed the invention as claimed. For biomolecules, examples of identifying characteristics sufficient to meet the written description requirement include "binding specificity." M.P.E.P. § 2163 (II)(A)(3)(a). Such a disclosure of a structural element (such

as a binding motif sequence) combined with a showing of a relationship between the structure and its function (a particular binding) satisfies the written description requirement for a method based on binding.

Disclosure of any combination of identifying characteristics that distinguish what is claimed from other materials leads the skilled person to conclude that the inventors had possession of the invention. M.P.E.P. § 2163 (II)(A)(3)(a)(i)(C)(2); Regents of University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568; 43 U.S.P.Q. 2d 1398, 1406 (Fed. Cir. 1997). Applicants have shown that the structure of the disclosed binding motif, which is provided in the specification, correlates with the function of binding that is used in the claimed assay method. As the Eli Lilly case makes clear, although simply naming the type of material (e.g. "polypeptide which binds nuclear hormone receptors") is not a description of that material, a description of the molecules (cDNA in the case of Eli Lilly) may be achieved by recitation of a sequence which defines a representative number of the molecules or a recitation of structural features common to the members of the genus. Here, Applicants have provided a sequence common to all members of a genus which is a chemical/structural and functional identifyer of the molecules. Written description may be satisfied "by relevant, identifying characteristics... sufficient to show the applicant was in possession of the claimed genes." M.P.E.P. § 2163 (II)(A)(3)(a)(ii). Written description need only be so specific as to lead one of ordinary skill to the class of compounds which are claimed. Id. Here, the specification as originally filed describes all the necessary common attributes and features of the class of compounds which may be used with the invention. One of skill would know how to construct the necessary molecules for the assay and potential infringers would know whether a particular

compound fell within the claims. That is all that is required of Applicants to meet the written description requirement of 35 U.S.C. §112, first paragraph. Applicants therefore request that the Office withdraw the rejection of the claims on the basis of lack of written description under 35 U.S.C.§112, first paragraph.

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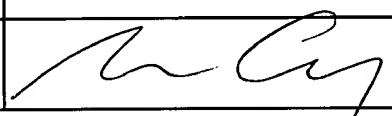
SIGNATURE			DATE	12/2/02	

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Attachments: Marked-Up Version of Amended Claims

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